SUPPORTING STATEMENT
United States Patent and Trademark Office
Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures
OMB CONTROL NUMBER 0651-0024
2025

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

Patent applications that contain nucleotide and/or amino acid sequence disclosures falling within the definitions of 37 CFR § 1.831 (for applications filed on or after July 1, 2022) or 37 § CFR 1.821(a) (for applications filed on or before June 30, 2022) must include, as a separate part of the application disclosure, a copy of the sequence listing in accordance with the requirements in 37 CFR §§ 1.831-1.835 or 37 CFR §§ 1.821-1.825, respectively. Applicants may submit sequence listings for both U.S. and international patent applications. For more information concerning the submission of sequence listings in international applications, see the Patent Cooperation Treaty (PCT) Rules 5.2 and 13*ter*, Annex C of the PCT Administrative Instructions, and section 1848 of the Manual of Patent Examining Procedure (MPEP) (9th ed., Rev. 01.2024, November 2024).

The USPTO uses the sequence listings during the examination process to determine the patentability of the invention claimed in the application. The USPTO also uses the sequence listings for pre-grant publication of applications and issued patents. Applicants use sequence listings when preparing both national and international patent applications that disclose nucleotide and/or amino acid sequences to provide a written description of the invention and to distinguish the claimed subject matter from the prior art.

This information collection only covers the submission of the sequence listing information itself. Information pertaining to the initial filing of U.S. patent applications is collected under OMB Control Number 0651-0032 (Initial Patent Applications), and information pertaining to the initial filing of international applications is collected under OMB Control Number 0651-0021 (Patent Cooperation Treaty).

Sequence listings for applications having a filing date of on or after July 1, 2022, must be submitted in XML format in accordance with 37 §§ CFR 1.831-1.835. The submission of a sequence listing in XML format must be made either electronically via the USPTO patent electronic filing system (currently Patent Center) as an XML file not exceeding 100MB without file compression, or as an XML file on a read-only optical disc in accordance with 37 CFR § 1.834(b)(2).

Sequence listings may still be filed in applications having a filing date of on or before June 30, 2022, as amendments that meet the requirements of 37 CFR § 1.825. Sequence listings submitted as amendments in accordance with 37 CFR § 1.825 must be submitted as:

- An ASCII plain text file via Patent Center or on a read-only optical disc;
- A PDF file via Patent Center; or
- Physical sheets of paper.

When an amendment that meets the requirements of 37 CFR § 1.825 is submitted as a PDF or on physical sheets of paper in an application having a filing date of on or before June 30, 2022, the applicant may also need to submit a new or substitute computer readable form (CRF) copy of the sequence listing under 37 CFR §§ 1.821(e) and 1.824, with the amendment incorporated therein, if necessary, under 37 CFR §§ 1.825(a)(5)(ii) or (b)(6)(ii). Applicants may submit the CRF copy via Patent Center or on a read-only optical disc as provided in 37 CFR § 1.824(b). When a new or substitute CRF copy is necessary, applicants must submit a statement indicating that the CRF copy of the sequence listing is identical to the PDF or paper copy. This information collection also accounts for these CRF copy and statement requirements.

Table 1 provides the specific statutes and regulations authorizing the USPTO to collect the information discussed above:

Table 1: Information Requirements

Item No.	Requirement	Statute	Regulation
1	Sequence Listing in Application	35 U.S.C. 22	37 CFR §§ 1.821-1.825 (applications filed on or before June 30, 2022), 37 CFR §§ 1.831-1.835 (applications filed on or after July 1, 2022)

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The USPTO uses the sequence listings during the examination process to determine the patentability of the invention claimed in the application.

The USPTO also uses the sequence listings for pre-grant publication of applications and issued patents. In this regard, when an application containing sequence listings is published or issued as a patent, the associated nucleotide or amino acid sequence listings are disclosed to the public. Sequence listings that comprise files smaller than 600 KB are available through the standard application and patent search systems on the USPTO website. Sequence listings that comprise files larger than 600KB are available for public viewing or download through the Publication Site for Issued and Published

Sequences (PSIPS) on the USPTO website at seqdata.uspto.gov. Sequence listings that are too large to be loaded into the PSIPS sequence viewer are available at seqdata.uspto.gov/bulk. Please see sections 2419.02 and 2435 of the MPEP for more information.

In addition, the USPTO forwards copies of sequence listings from pre-grant patent application publications and issued patents to the National Center for Biotechnology Information for inclusion in the Genbank public database.

Applicants use sequence listings when preparing both national and international patent applications that disclose nucleotide and/or amino acid sequences to provide a written description of the invention and to distinguish the claimed subject matter from the prior art.

The information collected, maintained, and used in this collection is based on OMB and USPTO guidelines. This includes the basic information quality standards established in the Paperwork Reduction Act (44 U.S.C. Chapter 35), in OMB Circular A-130, and in the USPTO information quality guidelines.

Table 2 outlines how this collection of information is used by the public and the USPTO:

Table 2: Needs and Uses

Item No.	Form/ Function	Form No.	Needs and Uses
1	Sequence Listing in Application	No Form Associated	• Used by the public when preparing a U.S. or international patent application containing nucleotide and/or amino acid sequence information. • Used by the USPTO to determine the patentability of the invention claimed in an application. • Used by the USPTO to support publication of patent applications and issued patents.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Sequence listings for applications filed on or after July 1, 2022

Applicants must submit sequence listings as XML files, either by electronically transmitting the XML file through Patent Center, where the file does not exceed 100MB without compression, or on read-only optical discs.

Filers submitting sequence listings electronically through Patent Center upload the listings using a secure interface. Patent Center offers many potential benefits to filers, including the provision of an immediate electronic receipt. Electronic filing also eliminates the

inefficiencies of physically mailing, handling, routing, and storing sequence listings on paper or read-only optical discs.

Filers submitting sequence listings as XML files on read-only optical discs are advised to keep a back-up copy of the read-only optical disc and transmittal information for their own records.

A desktop software tool, WIPO Sequence, is available to support authoring, validating, and generating XML format sequence listings. WIPO Sequence is downloadable for free from https://www.wipo.int/en/web/standards/sequence/index. WIPO Sequence simplifies the creation of XML format sequence listings with a user-friendly interface so there is no need to directly edit an XML file. Using WIPO sequence to produce XML format sequence listings is not required, but is highly recommended.

Sequence listings for applications filed on or before June 30, 2022

Sequence listings may still be filed in applications having a filing date of on or before June 30, 2022, as amendments that meet the requirements of 37 CFR § 1.825. In addition to the USPTO's preferred option of submitting such an amendment as an ASCII plain text file, preferably via Patent Center, or alternatively on a read-only optical disc, the amendment may be submitted electronically through Patent Center as a PDF or on paper. When submitted as a PDF or on physical sheets of paper, the applicant may also need to submit a new or substitute CRF copy of the sequence listing, if necessary, under 37 CFR §§ 1.825(a)(5)(ii) or (b)(6)(ii). Applicants may submit the CRF copy via Patent Center or on a read-only optical disc.

4. **Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.**

This collection requires the duplication of a limited amount of identifying information (such as the applicant's name and application number), which is also provided on the patent application. However, the duplication of identification information is the most efficient way of accurately associating the sequence listing with the appropriate application case file.

5. **If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden**.

Although small businesses or other small entities submit the sequence listings covered by this information collection, the collection does not impose a significant economic impact on small businesses or other small entities. The same information is required from every applicant and is not available from any other source.

Moreover, for the fees associated with the item of information in this collection, the USPTO reduces the cost burden for small entities by offering reduced fee amounts for

persons, small business concerns, or nonprofit organizations that qualify as small entities (including micro entities) under 37 CFR § 1.27 (see 37 CFR § 1.29 for micro entity status). No significant burden is placed on small entities, in that small entities are simply required to identify themselves as such in order to obtain these benefits. An assertion of small entity status (or a certification of entitlement to micro entity status) only needs to be filed once in an application or patent.

6. **Describe the consequence to federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.**

This collection of information is required for the processing and examination of the respondent's patent application involving a nucleotide or amino acid sequence listing. This information could not be collected less frequently. If the information were not collected, the USPTO could not properly examine the associated application as required by 35 U.S.C. 131. Further, the collection of this information is necessary in order to publish the sequence listings accurately as part of the application or patent.

7. **Explain any special circumstances that would cause an information collection to be conducted in a manner:**
   - **requiring respondents to report information to the agency more often than quarterly;**
   - **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
   - **requiring respondents to submit more than an original and two copies of any document;**
   - **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
   - **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
   - **requiring the use of a statistical data classification that has not been reviewed and approved by OMB; • that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
   - **requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no special circumstances associated with this collection of information.

8. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years - even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The 60-Day *Federal Register* Notice was published on June 26, 2025 (90 FR 27284).[1] The comment period ended on August 25, 2025. The USPTO received no public comments in response to the notice.

The 30-Day *Federal Register* Notice was published on October 24, 2025 (90 FR 48553).[2] The comment period will end on November 24, 2025.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection does not involve a payment or gift to any respondent.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

[1] https://www.govinfo.gov/content/pkg/FR-2025-06-26/pdf/2025-11798.pdf.
[2] https://www.govinfo.gov/content/pkg/FR-2025-10-24/pdf/2025-19650.pdf.

Confidentiality

Confidentiality of patent applications is governed by statute (35 U.S.C. 122) and regulation (37 CFR §§ 1.11 and 1.14). The USPTO has a legal obligation to maintain the confidentiality of the contents of unpublished patent applications and related documents. Upon publication of an application or issuance of a patent, the patent application file is made available to the public, subject to the provisions for providing only a redacted copy of the file contents (37 CFR §§ 1.11(a) and 1.217). The item in this information collection is filed in a patent application. Accordingly, the USPTO will maintain the confidentiality of responses received under this information collection until the application in which it is filed publishes or issues as a patent.

Privacy Act System of Records Information

This information collection contains information which is subject to the Privacy Act. This information is collected on documents related to patent applications. Privacy Act Statements are included on these forms. The following System of Records Notice (SORN) provides privacy disclosures and information about the USPTO's handling of any personally identifiable information (PII) that may be included when submitting the information in this collection.

The applicable Privacy Act System of Records Notice for this information collection is COMMERCE/PAT-TM-7 Patent Application Files, available at 78 FR 19243 (March 29, 2013).[3] The purpose of PAT-TM 7 is to disclose how the USPTO intends to use, maintain, and protect the information that it has collected to carry out the duties of the USPTO to examine patent applications and issue patents. PAT-TM 7 includes all applicant records, including name, citizenship, residence, post office address, and other information pertaining to the applicant's activities in connection with the invention for which a patent is sought or has been granted.

Information in this system of records is derived from applicants for patent, including inventors, legal representatives for deceased or incapacitated inventors, and other persons authorized by law to make applications for patent. Patents applications are maintained in confidence as required by 35 U.S.C. 122(a) until the application is published or issued as a patent. Categories of records in the system comprise the following: oath or declaration of applicant including name, citizenship, residence, post office address, and other information pertaining to the applicant's activities in connection with the invention for which a patent is sought.

The information in SORN 7 is protected from disclosure to third parties in accordance with the Privacy Act until the application is published under 35 U.S.C. 122(b) or issued as a patent under 35 U.S.C. 153. Prior to application publication or patent issuance, the information in SORN 7 is protected from disclosure to third parties in accordance with the Privacy Act, except that disclosure is permitted for the following routine uses including, but not limited to: law enforcement in the event that the system of records indicates a violation or potential violation of law; a federal, state, local, or international agency, in response to its request; an agency, organization, or individual for the purpose of performing audit or oversight operations as authorized by law; non-federal personnel under contract to the agency; the Department of Justice for Freedom of Information Act (FOIA) assistance; a member of Congress working on behalf of an individual to whom the record pertains, when the individual has requested the member's assistance with respect to the subject matter of the record; the Office of Personnel Management (OPM) for personnel research purposes; and the Office of Management and Budget (OMB) for legislative coordination and clearance.

Privacy Impact Assessment

[3] https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf.

The data in this system of records may also be associated with an IT system that has a Privacy Impact Assessment (PIA) which provides additional information about how data is handled and maintained. The following IT systems may include data collected as a part of this information collection:

Data Conversion Laboratory Patent Support (DCLPS)
Enterprise Data Services System – Databricks (EDS-DBX)
Flatirons Patent Data and Document Management (Flatirons PDDM)
Global Patent Solutions (GPS) System
International Data Exchange Cloud (IDE-C)
Information Delivery Product (IDP)
Information Dissemination Support System (IDSS)
Landon IP Information System
Open Data-Big Data Master System (OD-BD MS)
Patent Capture and Application Processing System - Examination Support (PCAPS-ES)
Patent Capture and Application Processing System - Initial Processing (PCAPS-IP)
Patent End to End (PE2E)
Patent Trial and Appeal Board End to End (PTAB E2E)
Patent Search System - Primary Search and Retrieval (PSS-PS)
Patent Business and Content Management Services (PBCMS) EventHub
Patent Exam Center (PEC)
Patent Examination Data Search (PEDS)
Patent Public Search (PPUBS)
Patent Search System - Primary Search and Retrieval System (PSS-PS)
Patent Trial and Appeal Case Tracking System (P-TACTS)
Reed Technology and Information Services Inc. (RTIS) Patent Data Capture (PDCap)
Reed Technology and Information Services Inc. (RTIS) Public Data Dissemination (RTIS PDD)
Serco Patent Processing System (PPS)
Trilateral Network (TRINET)
VASTEC Data Conversion System (VASTEC DCS)

More information about these PIAs is available through the Department of Commerce's Office of Privacy and Open Government.[4]

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

[4] https://www.commerce.gov/opog/privacy/PIA/USPTO-PIA.

None of the required information in this collection is considered to be sensitive.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**
- **If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**
- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included under 'Annual Cost to Federal Government'.**
- **Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information.**

Table 3 calculates the burden hours and costs of this information collection to the public, based on the following factors:

- **Respondent Calculation Factors**
  The USPTO estimates that it will receive approximately 30,000 responses per year from 30,000 respondents for this information collection, with approximately 55% of these responses submitted by small entities.

  The USPTO estimates that approximately 99% of the responses in this collection will be submitted electronically via Patent Center, which customers may access through the USPTO website.

- **Burden Hour Calculation Factors**
  The USPTO estimates that it takes the public approximately 6 hours to gather the necessary information, prepare the appropriate document(s), and submit the item to the USPTO. Using these burden factors, USPTO estimates that the total respondent hourly burden for this information collection is 180,000 hours per year.

- **Cost Burden Calculation Factors**
  The USPTO uses a professional rate of $447 per hour for respondent cost burden calculations, which is the median rate for intellectual property attorneys in private

firms as shown in the 2023 *Report of the Economic Survey* published by the American Intellectual Property Law Association (AIPLA).

Using these hourly rates, the USPTO estimates that the total respondent cost burden for this information collection is $80,460,000 per year.

Table 3: Total Burden Hours and Hourly Costs to Private Sector Respondents

Item No.	Item	Estimated Annual Respondents (a)	Responses per Respondent (b)	Estimated Annual Responses (a) x (b) = (c)	Estimated Time for Response (hours) (d)	Estimated Burden (hour/year) (c) x (d) = (e)	Rate[5] ($/hour) (f)	Estimated Annual Respondent Cost Burden (e) x (f) = (g)
1	Sequence Listing in Application	30,000	1	30,000	6	180,000	$447	$80,460,000
	Totals	**30,000**	**- - -**	**30,000**	**- - -**	**180,000**	**- - -**	**$80,460,000**

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

- **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collections services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

This collection has non-hourly cost burdens in both fees paid by the public and associated postage costs for mailing items to USPTO.

[5] 2023 Report of the Economic Survey, published by the Committee on Economics of Legal Practice of AIPLA; pg. F–41. The USPTO uses the average billing rate for intellectual property work in all firms which is $447 per hour (https://www.aipla.org/home/news-publications/economic-survey).

The total non-hour respondent cost burden for this collection is estimated to be $336,973 per year, which includes $333,853 in fees and $3,120 in postage.

Filing Fees

Sequence listings for applications filed on or after July 1, 2022

Applicants must submit sequence listings as XML files, either by electronically transmitting the XML file through Patent Center, where the file does not exceed 100MB without compression, or on read-only optical discs. Accordingly, the size fees for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR §§ 1.16(s), 1.52(f), and 1.492(j), from which XML file submissions via Patent Center or read-only optical discs are excluded, do not apply to sequence listings filed in applications having a filing date of on or after July 1, 2022.

Sequence listings for applications filed on or before June 30, 2022

Sequence listings may still be filed in applications having a filing date of on or before June 30, 2022, as amendments that meet the requirements of 37 CFR § 1.825. The USPTO prefers that such an amendment be submitted as an ASCII plain text file via Patent Center or a read-only optical disc. If so, the size fees for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR §§ 1.16(s) and 1.52(f), from which ASCII plain text file submissions via Patent Center or read-only optical discs are excluded, do not apply.

However, the USPTO permits the amendment to be submitted electronically through Patent Center as a PDF or on paper. When doing so, the submission may incur a size fee for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 §§ CFR 1.16(s) and 1.52(f).

Specifically, under 37 CFR § 1.16(s), if a patent application inclusive of a sequence listing amendment filed as a PDF or on paper exceeds 100 pages, the application size fee is $450 ($180 for small entities, $90 for micro entities) for each additional 50 pages or fraction thereof. For the purposes of this calculation, the USPTO assumes that the average length of a sequence listing filed as a PDF or on paper is 150 pages, which would result in a total size fee of three times the $450 application size fee under 37 CFR § 1.16(s), i.e., $1,350 ($540 for small entities, $270 for micro entities) for applications that are at least 100 pages long prior to the sequence listing amendment. The USPTO estimates that 67 respondents annually will file sequence listing amendments as a PDF or on paper that will require the payment, on average, of $1,350 for the undiscounted utility application size fee under 37 CFR § 1.16(s). The USPTO presents this estimate in Table 4 below as 201 responses annually for the undiscounted utility application size fee under 37 CFR §§ 1.16(s) of $450 (67 respondents paying the fee three times). Table 2 also reflects similar adjustments for the small and micro entity discounted utility application size fee under 37 CFR § 1.16(s).

Mega-sequence listings

Regardless of application filing date, the USPTO's receipt in electronic form of a very lengthy sequence listing (mega-sequence listing) in an application under 35 U.S.C. 111 or 371 is subject to the fee under 37 CFR § 1.21(o). In particular, the first receipt by the USPTO of a sequence listing in electronic form ranging in size from 300MB to 800MB (without file compression) incurs the fee under 37 CFR § 1.21(o)(1). The first receipt by the USPTO of a sequence listing in electronic form exceeding 800MB (without file compression) incurs the fee under 37 CFR § 1.21(o)(2).

Late furnishing fee in PCT applications

Where a PCT applicant has not provided a sequence listing, and the USPTO acts as the International Searching Authority (ISA) or International Preliminary Examining Authority (IPEA), the USPTO may invite the applicant to furnish a sequence listing, with a late furnishing fee under 37 CFR §§ 1.445(a)(5) and 1.482(c), under PCT Rule 13*ter*. See section 1848(I) of the MPEP for more information.

Table 4: Filing Fees

Item No.	Fee Code	Item	Estimated Annual Respondents Paying a Fee (a)	Number of Responses Per Respondent (b)	Estimated Annual Number of Fees Being Paid (c)	Filing Fee ($) (d)	Non-hourly Cost Burden (c) x (d) = (e)
1	1081	Utility application size fee under 37 CFR § 1.16(s) (undiscounted entity)	67	3	201	$450	$90,450
1	2081	Utility application size fee under 37 CFR § 1.16(s) (small entity)	82	3	246	$180	$44,280
1	3081	Utility application size fee under 37 CFR § 1.16(s) (micro entity)	1	3	3	$90	$270
1	1091	Submission of sequence listings of 300MB to 800MB (undiscounted entity)	10	1	10	$1,140	$11,400
1	2091	Submission of sequence listings of 300MB to 800MB (small entity)	1	1	1	$456	$456
1	3091	Submission of sequence listings of 300MB to 800MB (micro entity)	1	1	1	$228	$228
1	1092	Submission of sequence listings of more than 800MB (undiscounted entity)	1	1	1	$11,290	$11,290
1	2092	Submission of sequence listings of more than 800MB (small entity)	1	1	1	$4,516	$4,516
1	3092	Submission of sequence listings of more than 800MB (micro entity)	1	1	1	$2,258	$2,258

Item No.	Fee Code	Item	Estimated Annual Respondents Paying a Fee (a)	Number of Responses Per Respondent (b)	Estimated Annual Number of Fees Being Paid (c)	Filing Fee ($) (d)	Non-hourly Cost Burden (c) x (d) = (e)
1	1627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (undiscounted entity)	230	1	230	$345	$79,350
1	2627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (small entity)	645	1	645	$138	$89,010
1	3627	Late Furnishing Fee for Providing a Sequence Listing in Response to an Invitation Under PCT Rule 13*ter* (micro entity)	5	1	5	$69	$345
		Totals	**1,045**	**- - -**	**1,345**	**- - -**	**$333,853**

Postage Costs

Only sequence listings filed as 37 CFR § 1.825 amendments in applications having a filing date of on or before June 30, 2022, may be submitted by mail through the United States Postal Service. Accordingly, the USPTO expects that at most 1% of the responses in this collection will be submitted by mail. The USPTO estimates that the average postage cost for a mailed submission, using a Priority Mail legal flat rate envelope, will be $10.40. The USPTO estimates approximately 300 submissions per year may be mailed to the USPTO, for an estimated total postage cost of $3,120 per year.

14. Provide estimates of annualized costs to the federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies may also aggregate cost estimates from Items 12, 13, and 14 in a single table.

The USPTO employs GS-6, GS-12, and GS-13 employees to process submissions for this information collection.

The USPTO estimates that the cost of a GS-6, step 1 employee is $33.59 per hour (GS hourly rate of $24.65 with 36.25% ($8.94) added for benefits and overhead).

The USPTO estimates that the cost of a GS-12, step 1 employee is $66.20 per hour (GS hourly rate of $48.59 with 36.25% ($17.61) added for benefits and overhead).

The USPTO estimates that the cost of a GS-13, step 1 employee is $78.73 per hour (GS hourly rate of $57.78 with 36.25% ($20.95) added for benefits and overhead).

The average hourly rate of these employees is $59.51.

The USPTO estimates that it takes employees 24 minutes (0.40 hours) to process items in this collection.

Table 5 calculates the burden hours and costs to the federal government for processing this information collection:

Table 5: Burden Hour/Cost to the Federal Government

Item No.	Item	Estimated Annual Responses (a)	Estimated Burden Hours (b)	Estimated Hourly Burden (a) x (b) = (c)	Rate[6] ($/hr) (d)	Total Federal Government Cost (c) x (d) = (e)
1	Sequence Listing in Application	30,000	0.40 (24 minutes)	12,000	$59.51	$714,120
	Totals	**30,000**	**- - -**	**12,000**	**- - -**	**$714,120**

15. Explain the reasons for any program changes or adjustments reported on the burden worksheet.

Table 6: ICR Summary of Burden

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	30,000	0	0	1,450	0	28,550
Annual Time Burden (Hr)	180,000	0	0	8,700	0	171,300
Annual Cost Burden ($)	336,973	0	0	-924,514	0	1,261,487

Changes in Collection Since Previous Renewal

Since the previous renewal by OMB in 2022, the USPTO has filed two nonsubstantive change requests (change worksheets) making changes to this information collection.

The first change worksheet was submitted to OMB in March 2023. The USPTO changed the filing fees collected by this collection as part of RIN 0651-AD66 (Reducing Patent Fees for Small Entities and Micro Entities Under the Unleashing American Innovators Act of 2022). This change resulted in a decrease of $240,438 to this collection's non-hourly annual cost burden.

[6] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB_h.pdf.

The second change worksheet was submitted to OMB in November 2024. The USPTO adjusted the filing fees in support of RIN 0651-AD64 (Setting and Adjusting Patent Fees During Fiscal Year 2025). This adjustment resulted in an increase of $17,989 to this collection's non-hourly annual cost burden.

Change in Responses and Hourly Burden due to Adjustment in Agency Estimate

The total number of responses has increased by 1,450 due to estimated fluctuations in the number of submissions in this information collection. This increase in the number of respondents and responses results in an increase of 8,700 hours in the annual time burden estimates.

Change in Annual Non-hour Costs due to Adjustment in Agency Estimate

For this renewal, the USPTO estimates that the total annual non-hour costs will decrease by $924,514 from the previous approval. This decrease is largely due to the fact that sequence listings for applications filed on or after July 1, 2022, must be submitted as XML files, either by electronically transmitting the XML file through Patent Center, where the file does not exceed 100MB without compression, or on read-only optical discs. Accordingly, the size fees for excess pages under 35 U.S.C. 41(a)(1)(G) and 37 CFR §§ 1.16(s), 1.52(f), and 1.492(j), from which XML file submissions via Patent Center or read-only optical discs are excluded, do not apply to sequence listings filed in applications having a filing date of on or after July 1, 2022.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

The USPTO does not plan to publish this information for statistical use.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

There are no forms in this information collection on which to display the OMB Control Number and the expiration date of OMB approval.

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

This collection of information does not include any exceptions to the certificate statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.